Remarks

Claims 123-125, 127 and 129-166 were pending in the subject application. By this Amendment, applicants have canceled claims 125, 129-131, 134-151, 154 and 158-166, and amended claims 123, 133, 152 and 157. Accordingly, claims 123-124, 127, 132-133, 152-153 and 155-157 are pending in the subject application.

In Section 4 of the September 22, 2003 Office Action, the Examiner noted that Exhibits 6 through 14 and a copy of 1449 enclosed in the amendment filed June 27, 2003 were missing.

In response, applicants resubmit Exhibits 6-14 of the June 27, 2003 Amendment including the copy of the form PTO-1449, herewith.

Rejection of Claims 123-125, 127, 129-142 and 144-166 under 35 U.S.C. §112, First Paragraph, Enablement Requirement

In Section 7 of the September 22, 2003 Office Action, the Examiner rejected claims 123-125, 127, 129-142, and 144-166 under 35 U.S.C. § 112, first paragraph, alleging that the specification, while being enabling for a method of treating multiple sclerosis in a mammal comprising administering the mammal a purified polypeptide comprising the amino acid sequence of SEQ ID NO: 2 and 7, does not reasonably provide enablement for (1) a method of treating *any* autoimmune disease, *any* B cell mediated autoimmune disease, or *any* T cell mediated autoimmune disease or any autoimmune disease such as the ones recited in claims 134 and 144, *any* graft versus host disease, *any* host versus graft disease, or *any* delayed type hypersensitivity in any mammal comprising administering to the mammal a purified polypeptide having the amino acid sequence set forth in SEQ ED

NO: 2, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7 or a mixture of purified polypeptides as set forth in claims 123-142, and 144-151; and (2) a method of delaying the onset of any autoimmune disease, *any* B cell mediated autoimmune disease, or *any* T cell mediated autoimmune disease or any autoimmune disease such as the ones recited in claim 158, *any* graft versus host disease, *any* host versus graft disease, or *any* delayed type hypersensitivity in any mammal comprising administering to the mammal a purified polypeptide having the amino acid sequence set forth in SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 7 or a mixture of purified polypeptides as set forth in claims 152-166. The Examiner essentially reiterated the assertions set forth in the March 25, 2003 Office Action in support of the rejection.

In response, without conceding the correctness of the Examiner's comments and solely to advance the prosecution of the subject application, applicants have canceled claims 129-131, 134-142, 144-151 and 158-166, and amended claims 123, 133, 152 and 157 to recite a method of treating, and a method of delaying the onset multiple sclerosis comprising administering to the mammal an single polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 2 or SEQ ID NO: 7.

The Examiner has acknowledged in the enablement discussion of the September 22, 2003 Office Action that the specification enables claims for the method of treating or delaying the onset of multiple sclerosis in a mammal comprising administering to the mammal a purified polypeptide having the amino acid sequence set forth in SEQ ID NO: 2 or SEQ ID NO: 7. Accordingly, applicants respectfully submit that claims 123-

124, 127, 132-133, 152-153 and 155-157 as amended are enabled by the specification.

For the record, however, applicants maintain that their disclosure enables a method of treating, and a method of delaying the onset of, multiple sclerosis using polypeptides having an amino acid sequence as set forth in any of SEQ ID NOs.: 2, 4, 5, 6 or 7.

Rejection of Claims 123-125, 127, 129-142 and 144-166 under 35 U.S.C. §112, First Paragraph, Written Description Requirement

In Section 8 of the September 22, 2003 Office Action, the Examiner rejected claims 123-125, 127, 129-142, and 144-166 under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The Examiner alleged that the results in Table 14 show that only polypeptides SEQ ID NO: 2, and 7 block the progression of EAE while treatment with polypeptides of SEQ ED NO: 4, 5 and 6 fail to block the progression of EAE (see page 38). The Examiner alleged that treatment with polypeptides of SEQ ID NO: 4-6 does not prevent EAE because it has a mean onset of EAE at days 11.7, 14, and 12, respectively, as compared to control (11.3 days). The Examiner alleged that the delayed onset of disease for polypeptides of SEQ ID NO: 4 and 6 is not significantly different than the control.

The Examiner concluded that with the exception of the specific method of treating multiple sclerosis by administering the

specific polypeptides mentioned above, there is insufficient written description about the method *of treating* or delaying the onset of any other autoimmune disease such as any B cell mediated autoimmune disease, any T cell mediated autoimmune disease, any demyelinating disease, any inflammatory disease, rheumatoid arthritis, osteoarthritis, autoimmune hemolytic anemia, autoimmune oophoritis, autoimmune thyroiditis, autoimmune uveoretinitis, Crohn's disease, chronic immune thrombocytopenic purpura, colitis, contact sensitivity disease, diabetes mellitus, idiopathic myxedema, myasthenia gravis, psoriasis, pemphigus vulgaris, or systemic lupus erythematosus, including graft versus host disease (GVHD), host versus graft disease (HVGD) or delayed-type hypersensitivity such as such as poison ivy, poison oak or chemical contact, tuberculosis, leprosy, leishmaniasis, deep fungal infection, etc as defined on page 18 of the specification comprising administering to the mammal a purified polypeptide having the amino acid sequence set forth in SEQ ID NO: 2, 4, 5, 6, 7 or a mixture thereof.

The Examiner stated that the specification discloses only a method of treating or delaying the onset of one autoimmune disease, which is multiple sclerosis by administering polypeptides selected from the group consisting of SEQ ED NO: 2, 4, 5, 6 and 7 using the EAE as a model for multiple sclerosis.

In response, without conceding the correctness of the Examiner's comments and solely to advance the prosecution of the subject application,, applicants have amended claims 123-125, 127, 129-133 and 152-157 to recite a method of treating, and a method of delaying the onset of, multiple sclerosis comprising administering polypeptides having the amino acid sequence set forth in SEQ ID NO:2 or SEQ ID NO:7. The Examiner

has acknowledged that the specification does provide sufficient written description of a method of treating and a method of delaying the onset of multiple sclerosis by administering polypeptides having the amino acid sequence set forth in SEQ ID NO:2 or SEQ ID NO:7. Accordingly, claims 123-124, 127, 132-133, 152-153 and 155-157, as amended, recite subject matter described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

For the record, however, applicants maintain that their disclosure provides a written description for a method of treating, and a method of delaying the onset of, multiple sclerosis using polypeptides having an amino acid sequence as set forth in any of SEQ ID NOs.: 2, 4, 5, 6 or 7.

Rejection of Claims 157-165 under 35 U.S.C. §112, First Paragraph, Written Description Requirement

In Section 11 of the September 22, 2003 Office Action, the Examiner rejected that claims 157-165 under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner stated that this is a new matter rejection.

The Examiner alleged that the "consisting essentially of" in Claim 157 represents a departure from the specification and the claims as originally filed. The Examiner alleged that the passages pointed out by applicant in the amendment filed

6/27/03 do not provide a clear support for the said phrase.

In response, without conceding the correctness of the Examiner's comments and solely to advance the prosecution of the subject application, applicants have amended claim 157 to recite "... comprising a single purified polypeptide...and a pharmaceutically acceptable carrier." Support for this amendment may be found in the specification on page 16, lines 1-2 which recites, "[T]he present molecular weight markers can be formulated into pharmaceutical compositions containing a pharmaceutical acceptable carrier." M.P.E.P. § 2111.03 provides that "containing" is a synonym for "comprising". Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims 157 under 37 U.S.C. §112, first paragraph.

Rejection of Claims 123-125, 127, 129-142 and 144-166 under 35 U.S.C. §112, Second Paragraph

In Section 13 of the September 22, 2003 Office Action, the Examiner rejected claims 123-125, 127, 129-142, and 144-166 under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner alleged that the phrase "or a mixture of the purified polypeptides" in claims 123, 133, 142, 157 and 166 is ambiguous, indefinite and not clear which polypeptides in the mixture that applicants intend to claim. The Examiner alleged that one of ordinary skill in the art cannot appraise the metes and bounds of the claimed invention.

In response, without conceding the correctness of the Examiner's comments and solely to advance the prosecution of the subject application, applicants have cancelled claims 142 and 166, and have also amended claims 123, 133, 152 and 157 to recite "a single purified polypeptide...". Support for this amendment can be found, for example, on page 37, line 24 to page 38, line 30 of the specification where the testing of the polypeptides are described. Specifically, on page 38, lines 8-9, the specification recites "Each antigen being tested was included in the encephalitogenic inoculum..." These antigens are listed on Table 14 on page 38. The correspondence between the TV # used in the Table 14 and the SEQ ID NO: of the claims is provided in Table 1 on page 14 (as amended August 1, 2002). Therefore, the amended claims clearly describe which peptides are used in the pharmaceutical composition. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection of claims under 35 U.S.C. 112, second paragraph because claim 157 as amended recites subject matter described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

In sum, to advance the subject application to allowance, applicants have canceled claims 124, 129-131, 134-151, 154 and 158-166. Applicants have also amended claims 123, 133, 152 and 157 to recite methods of treating or delaying the onset of multiple sclerosis comprising administering polypeptides comprising amino acids having a sequence of SEQ ID NO: 2 or SEQ ID NO: 7. Claims 124, 127, 132, 153 and 155-156 all depend directly on either claim 123 or 152. For the reasons outline above, the applicants respectfully request that the

Examiner reconsider and withdraw the rejections set forth in the September 22, 2003 Office Action.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is deemed necessary, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Gary J. Gershik 12/22/03

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